

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAYCOL PRODUCTS LITIGATION

MDL No. 1431 (MJD/SER)

This Document Relates to the following cases:

MARK STODGHILL, Individually and as
Personal Representative of the ESTATE OF
RALPH STODGHILL,

Court File No. 011-CV-01313 MJD/SER

Plaintiff,
v.

**ANSWER OF DEFENDANT
BAYER CORPORATION**

BAYER AG and BAYER CORPORATION,

Defendants.

Defendant Bayer Corporation (“Bayer”), for its Answer (“Answer”) to Plaintiff’s Complaint (the “Complaint”), states as follows:

1. Bayer admits, on information and belief, that Plaintiff is a citizen of Oklahoma. Bayer admits that Plaintiff brings this action seeking certain relief, but Bayer denies that Plaintiff is entitled to any relief. Bayer is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 1.

2. Bayer admits that Bayer AG is a foreign corporation with its principal place of business in Leverkusen, Germany. Bayer denies the remaining allegations in the first sentence of Paragraph 2. Because of the vagueness and ambiguity of the remaining allegations in Paragraph 2 of the Complaint, Bayer is without knowledge or information sufficient to form a belief as to the truth of those allegations. For a further response, Bayer states that, to the extent that the Complaint contains allegations directed to Bayer AG by use of the term “Defendants” or

otherwise, no answer is required by Bayer. Bayer therefore makes no response in this Answer to allegations that are directed to Bayer AG.

3. Bayer admits that Bayer is authorized to do business in Pennsylvania and that Bayer does business in Pennsylvania. Bayer further admits that Bayer's principal place of business is located in Pittsburgh, Pennsylvania. Bayer further admits that, prior to August 8, 2001, Bayer promoted, marketed, distributed and sold Baycol®, a prescription medication also known as cerivastatin sodium, in the United States, including in Oklahoma. Bayer denies that it developed or manufactured Baycol®. Bayer denies the remaining allegations in Paragraph 3 of the Complaint.

4. The allegations in Paragraph 4 of the Complaint state conclusions of law to which no response is required. To the extent that a response is required, Bayer admits, on information and belief, that this Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332. Bayer denies that Plaintiff is entitled to any relief and denies any remaining allegations in Paragraph 4.

5. Bayer denies the allegations in Paragraph 5.

6. The allegations in Paragraph 6 of the Complaint state conclusions of law to which no response is required. To the extent that a response is required, Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6.

7. Bayer denies the allegations in Paragraph 7.

8. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8.

9. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9, but denies that Plaintiff's Decedent's alleged injuries were caused by Baycol®.

10. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10, but denies that Plaintiff's Decedent's alleged injuries were caused by Baycol®.

11. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11, but denies that Plaintiff's Decedent's alleged injuries were caused by Baycol®.

12. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12, but denies that Plaintiff's Decedent's alleged injuries were caused by Baycol®.

13. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13, but denies that Plaintiff's Decedent's alleged injuries were caused by Baycol®.

14. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14, but denies that Plaintiff's Decedent's alleged injuries were caused by Baycol®.

15. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 15, but denies that Plaintiff's Decedent's death was caused by Baycol®.

16. Bayer denies the allegations in Paragraph 16.

FIRST CAUSE OF ACTION

17. In response to Paragraph 17 of the Complaint, Bayer incorporates by reference its responses to all preceding paragraphs of the Complaint as if set forth herein in full.

18. Bayer denies the allegations in Paragraph 18 of the Complaint.

19. Bayer denies the allegations in Paragraph 19 of the Complaint.
20. Bayer denies the allegations in Paragraph 20 of the Complaint.
21. Bayer denies the allegations in Paragraph 21 of the Complaint.
22. Bayer denies the allegations in Paragraph 22 of the Complaint, including subparagraphs (a) through (e).

SECOND CAUSE OF ACTION

23. In response to Paragraph 23 of the Complaint, Bayer incorporates by reference its responses to all preceding paragraphs of the Complaint as if set forth herein in full.
24. The allegations in Paragraph 24 state legal conclusions to which no response is required. To the extent that a response is required, Bayer denies that it violated any applicable duty relating to Baycol® or the design, research, development, testing, inspection, labeling, preparation for use, manufacture, sale or distribution of Baycol®, and Bayer denies that Baycol® was dangerous, as alleged in the Complaint. Bayer denies that it designed, developed or manufactured Baycol®. Because of the vagueness and ambiguity of the remaining allegations in paragraph 24, Bayer is without knowledge or information sufficient to form a belief as to the truth of those allegations.
25. Bayer denies the allegations in Paragraph 25 of the Complaint.
26. Bayer denies the allegations in Paragraph 26 of the Complaint.
27. Bayer denies the allegations in Paragraph 27 of the Complaint, including subparagraphs (a) through (e).
28. Bayer denies the allegations in Paragraph 28 of the Complaint.
29. Bayer denies the allegations in Paragraph 29 of the Complaint.
30. Bayer denies the allegations in Paragraph 30 of the Complaint.

31. Bayer denies the allegations in Paragraph 31 of the Complaint, including subparagraphs (a) through (e).

THIRD CAUSE OF ACTION

32. In response to Paragraph 32 of the Complaint, Bayer incorporates by reference its responses to all preceding paragraphs of the Complaint as if set forth herein in full.

33. Bayer denies the allegations in Paragraph 33 of the Complaint.

34. Bayer denies that Plaintiff is entitled to any relief in this action, including but not limited to the specific items of relief requested by Plaintiff in the "Wherefore" clause of the Complaint, or elsewhere in the Complaint.

35. Bayer denies each and every allegation in the Complaint that relates or is directed to Bayer unless such allegations are expressly admitted in this Answer.

ADDITIONAL DEFENSES

1. Plaintiff's Complaint, and each and every count contained therein, fails to state a cause of action or claim upon which relief can be granted.

2. Some or all of Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and/or statutes of repose.

3. Plaintiff's claims may be barred, in whole or in part, because Plaintiff failed to give timely notice pursuant to Minn. Stat. §§ 604.04 and 336.2-607.

4. Plaintiff's claims are barred, in whole or in part, by laches, waiver and/or estoppel.

5. Plaintiff's claims are barred, in whole or in part, by Plaintiff's and/or Plaintiff's Decedent's failure to mitigate Plaintiff's and/or Plaintiff's Decedent's alleged damages.

6. The acts and omissions of Plaintiff and/or Plaintiff's Decedent caused and/or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrines of contributory negligence and/or comparative negligence. Plaintiff's recovery, if any, therefore is barred or should be apportioned in accordance with applicable law.

7. The alleged injuries sustained by Plaintiff and/or Plaintiff's Decedent, if any, were caused, in whole or in part, by pre-existing physical, medical, and/or physiological conditions, for which Bayer has no legal responsibility.

8. If Plaintiff and/or Plaintiff's Decedent suffered injuries as alleged in the Complaint, which is expressly denied, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly assumed by Plaintiff and/or Plaintiff's Decedent. Plaintiff's recovery accordingly is barred or should be reduced by Plaintiff's and/or Plaintiff's Decedent's assumption of the risk.

9. If the injuries claimed by Plaintiff were related to the use of Baycol®, which is expressly denied, any such injuries were the result of an idiosyncratic or allergic reaction to Baycol®.

10. The injuries and damages claimed by Plaintiff, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Bayer was not the proximate and/or competent producing cause of such alleged injuries and damages.

11. The injuries and damages claimed by Plaintiff, if any, are barred or must be reduced because those damages arose from the acts or omissions of persons or entities other than Bayer for whom Bayer has no legal responsibility.

12. If Plaintiff and/or Plaintiff's Decedent sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the

unforeseeable alteration, improper handling or other unforeseeable misuse, or use inconsistent with the labeling of the prescription drug Baycol®. Plaintiff's recovery is accordingly barred.

13. The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including Bayer.

14. Plaintiff's claims are barred because the benefits of Baycol® outweighed the risks, if any, that might be associated with the product.

15. The claims in the Complaint are barred in whole or in part by the learned intermediary doctrine.

16. Plaintiff's Complaint fails to state a claim upon which relief can be granted in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing and sale of Baycol®, including but not limited to adequate warnings and instructions with respect to the product's use included in the product's package inserts and other literature, conformed to the applicable state of the art. Baycol®, including its labeling approved by the FDA, complied with the state of scientific and medical knowledge available at the time. Plaintiff's recovery accordingly is barred.

17. Plaintiff's claims are barred because Baycol® was neither defective nor unreasonably dangerous in its design, manufacture or marketing and was reasonably safe and reasonably fit for its intended uses, thereby barring Plaintiff's recovery.

18. The warnings and instructions accompanying Baycol® at the time of the occurrence or injuries alleged by Plaintiff were legally adequate warnings and instructions.

19. Plaintiff's claims are barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited to, § 402A, comment k.

20. Bayer gives notice that to the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Complaint, Bayer intends to rely upon same in defense of this action.

21. The prescription drug Baycol® complied with the applicable product safety regulations promulgated by the FDA. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of this prescription drug, and that it was neither defective nor unreasonably dangerous. Plaintiff's recovery is accordingly barred.

22. Any claims by Plaintiff relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government.

23. Plaintiff's claims are barred in whole or in part because the commercial speech relating to Baycol® is protected under the First Amendment of the United States Constitution and the applicable state constitution.

24. Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

25. Plaintiff's claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution by reason of the federal regulation of prescription drug manufacturing, testing, marketing, and labeling.

26. Plaintiff cannot state a claim upon which relief may be granted with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiff is subject to the exclusive regulation of the FDA.

27. This Court should abstain from adjudicating Plaintiff's claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

28. Plaintiff and/or Plaintiff's Decedent did not detrimentally rely on any labeling, warnings or information concerning Baycol®.

29. Applicable law does not recognize a post-sale duty to warn in the present circumstances. Accordingly, the Complaint fails to state a claim upon which relief may be granted for inadequate post-sale marketing or post-sale duty to warn.

30. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

31. To the extent that Plaintiff's Complaint seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under applicable law.

32. To the extent that Plaintiff's and/or Plaintiff's Decedent's claims have been settled or Plaintiff will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of Bayer, if any, should be reduced accordingly.

33. Plaintiff's claims may be barred, in whole or in part, due to res judicata, collateral estoppel, or by release of claims.

34. Plaintiff's Complaint fails to state a claim upon which relief can be granted as to costs.

35. Plaintiff's Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

36. Plaintiff's Complaint fails to state a claim upon which relief can be granted for several or joint and several liability.

37. Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

38. Bayer denies any conduct for which punitive or exemplary damages could or should be awarded and denies that sufficient evidence has been produced to support or sustain the imposition of punitive damages pursuant to the applicable standard(s) of proof.

39. Permitting recovery of punitive or exemplary damages in this case would be unconstitutionally vague and/or overbroad and would violate Bayer's constitutional rights as secured by the Fifth and Seventh Amendments to the United States Constitution, would violate its rights to due process and equal protection under the Fourteenth Amendment of the United States Constitution and the prohibition against excessive fines in the United States Constitution, and would contravene other provisions of the United States and Oklahoma Constitution and any applicable state constitution.

40. Plaintiff cannot recover punitive or exemplary damages against Bayer because such an award, which is penal in nature, would violate Bayer's constitutional rights under the United States Constitution and any applicable state constitution, unless Bayer is afforded the same procedural safeguards as are criminal defendants, including but not limited to the right to avoid self incrimination, the right to forego production and disclosure of incriminating documents and the right to the requirement of a level of proof beyond a reasonable doubt.

41. Any imposition of punitive or exemplary damages in this case would contravene the Commerce Clause of the United States Constitution, in that such an award would constitute, if imposed, an undue and unreasonable burden on interstate commerce.

42. With respect to Plaintiff's demand for punitive or exemplary damages, Bayer specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under applicable state law or other applicable law.

43. Any award of punitive or exemplary damages is barred to the extent that it is inconsistent with the standards and limitations set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008).

44. No act or omission of Bayer was reckless or done intentionally with malice towards others, as alleged in the Complaint. No act or omission of Bayer was willful, wanton, malicious, intentional, or with malice toward others or reckless disregard for the rights of others, or posed substantial risk of serious injury and/or death. Accordingly, Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

45. Plaintiff is not the real party in interest or lacks the capacity and/or standing to bring the claims asserted in the Complaint.

46. Plaintiff's right to recover damages in this action, if any, is statutorily limited by the applicable state's wrongful death statute.

47. This Court is an improper venue for the trial of this action.

48. This Court is not the proper forum for the trial of this action and is not a convenient forum for the just adjudication of Plaintiff's claims.

49. Plaintiff's claims are subject to any limitations on damages, including but not limited to Oklahoma 23 O.S. § 9.1.

50. As applied, 23 O.S. § 9.1 is unconstitutionally vague and violates this Defendant's right of procedural and substantive due process under the United States Constitution because Section 9.1 permits punishment for conduct that reasonable people could conclude was lawful.

51. Plaintiff's right to recover damages in this action, if any, is statutorily limited by 12 O.S. § 1053.

52. Bayer adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with Bayer's defenses pleaded in this Answer.

53. Bayer reserves the right to amend its Answer and to assert separate and additional defenses to conform to such facts that may be revealed in discovery or otherwise.

WHEREFORE, Bayer prays that judgment be entered in its favor and against Plaintiff, that all claims against Bayer be dismissed with prejudice, and that Bayer be awarded its attorney's fees and costs and such other and further relief as the Court deems just and appropriate.

JURY TRIAL DEMAND

Bayer demands a trial by jury on all issues so triable.

Dated: December 7, 2011

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Counsel for Defendant Bayer Corporation

CERTIFICATE OF SERVICE

I, David L. Barlett, certify that a true and correct copy of the foregoing Answer of Defendant Bayer Corporation was electronically filed and served on December 7, 2011.

A handwritten signature in black ink, appearing to read "David L. Barlett", is written over a horizontal line.